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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,791	02/01/2001	Sherry L. Neuman	ISCR007/00US	2627
7590 Louis M Heidelberg Reed Smith LLP 2500 One Liberty Place Philadelphia, PA 19103-7301			EXAMINER NAJARIAN, LENA	
			ART UNIT	PAPER NUMBER
			3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/774,791

Applicant(s)

NEUMAN ET AL.

Examiner

Lena Najarian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 13-22, 24-31, 33, 34, 36, 38-40 and 42-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-22, 24-31, 33, 34, 36, 38-40, and 42-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 11/6/06.  
Claims 1-9, 13-22, 24-31, 33, 34, 36, 38-40, and 42-91 are pending. Claim 12 has been canceled. Claims 45, 46, 51, 57, 64, 84, and 85 have been amended.

***Claim Objections***

2. The objections to claims 51, 57, and 64 are hereby withdrawn due to the amendment filed 11/6/06.
3. Claim 13 is objected to because of the following informalities: Claim 13 improperly depends on canceled claim 12. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

4. The rejection of claims 45-46 and 84-85 under 35 U.S.C. 101 is hereby withdrawn due to the amendment filed 11/6/06.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an

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application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 79-84 and 86-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenblum (US 6,529,801 B1).

(A) Claims 79-83 and 86-87 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) The amendment to claim 84 was apparently made to overcome 101 issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-2, 9, 14-21, 24-27, 29-31, 33-34, 36, 38-40, 42-50, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US 6,421,650 B1) in view of Lion (US 6,330,491 B1).

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(A) Claims 1-2, 9, 14-21, 24-27, 29-31, 33-34, 36, 38-40, 42-44, 47-50, and 90 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) The amendments to claims 45 and 46 were apparently made to overcome the 101 issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claims as originally presented and/or in the manner in which the claims were interpreted by the Examiner when applying prior art within the previous Office Action. As such, these claims are rejected under the same rationale given in the prior Office Action, and incorporated herein.

9. Claims 3-8, 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US 6,421,650 B1) in view of Lion (US 6,330,491 B1) as applied to claims 1-2, 20-21, and 25-26 above, and further in view of Edelson et al. (5,737,539).

(A) Claims 3-8, 22, and 28 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

10. Claims 51-78, 85, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum (US 6,529,801 B1) in view of NCVHS (<http://www.ncvhs.hhs.gov/970416w2.htm>).

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(A) Claims 52-56, 58-63, 65-78 and 88 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

(B) The amendments to claims 51, 57, and 64 were apparently made to overcome the claim objections set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claims as originally presented and/or in the manner in which the claims were interpreted by the Examiner when applying prior art within the previous Office Action. As such, these claims are rejected under the same rationale given in the prior Office Action, and incorporated herein.

(C) The amendment to claim 85 was apparently made to overcome 101 issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

11. Claims 89, 13, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goetz et al. (US 6,421,650 B1) in view of Simcox (5,992,890).

(A) Claims 89, 13, and 91 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

***Response to Arguments***

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12. Applicant's arguments filed 11/6/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 11/6/06.

(1) Applicant argues at page 18 that Rosenblum fails to teach that the reason that a drug be "dispensed as written" is entered or received.

(2) Applicant argues at page 20 that one of skill in the art would not be motivated to combine the teachings of Goetz with those of Lion because Goetz requires a patient component. Direct communication between the physician component and pharmacist component would eliminate the function of the patient component, an essential feature of Goetz. Thus, the teachings of Goetz teach away from such a combination.

(3) Applicant argues at pages 20-21 that independent claims 20 and 36 require that a reason or motive for overriding the drug use evaluation alert be entered or received. Goetz says nothing about the reasons for overriding a drug use evaluation alert being entered or received. Thus, Goetz fails to teach this limitation found in Applicant's invention, therefore, the 103 rejection should be removed.

(4) Applicant argues at page 22 that Rosenblum is directed to a drug dispenser, not to the payment of claims as is the NCVHS reference. Thus, neither reference suggests that it should be combined with the other. Further, the motivation to combine cannot be found in the knowledge of one of skill in the art at the time of Applicant's invention. According to the NCVHS reference, DAW codes have been in existence since at least 1997. Thus, DAW codes had been in existence

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for years when the Rosenblum application was filed. Given that Rosenblum fails to teach entering or receiving the reason a drug should be dispensed as written further suggests that one of skill in the art would not have been motivated to combine the teachings of Rosenblum with the NCVHS reference at the time of Applicant's invention.

(5) Applicant argues at page 23 that neither Goetz nor Simcox teach an element of Applicant's invention: that the paper prescription contain the override.

(A) As per the first argument, the Examiner respectfully submits that Rosenblum discloses at Fig. 29B a field to enter a DAW code. As such, it is readily apparent that the reason is entered or received.

(B) In response to applicant's argument that one of skill in the art would not be motivated to combine the teachings of Goetz with those of Lion because Goetz requires a patient component, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(C) As per the third argument, the Examiner respectfully submits that Goetz teaches at col. 12, lines 8-21 "the ability to override the software warning and prescribe the drug anyway. This is routinely done by physicians today for minor potential interactions *when substitute drugs are either unavailable or would*



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*cause even more severe interactions ....* The patient is then able to read about the interaction....” As such, it is readily apparent that Goetz teaches that the reason for overriding a drug use evaluation alert (for example, the “minor potential interactions”) is entered or received.

(D) As per the fourth argument, the Examiner disagrees that neither reference suggests it should be combined with the other. Rosenblum discloses adjudicated claims (note step 4, Fig. 3 of Rosenblum). As such, Rosenblum is also directed to the payment of claims. Also, Rosenblum does disclose DAW codes (note Fig. 29B of Rosenblum). NCVHS goes further by defining the codes.

(E) As per the fifth argument, the Examiner respectfully submits that Goetz teaches the override and Simcox teaches the element of printing. Thus, the proper combination of these applied references results in the printing of the screen of Goetz.

### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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In

1-9-07

  
**C. LUKE GILLIGAN**  
**PRIMARY EXAMINER**  
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